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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,290	08/21/2001	Rosana Kapeller-Libermann	MINI-186	8801

7590

08/19/2005

Intellectual Property Group  
MILLENNIUM PHARMACEUTICALS INC.  
75 SIDNEY STREET  
CAMBRIDGE, MA 02139

EXAMINER

NASHED, NASHAAT T

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/935,290

Applicant(s)

KAPELLER-LIBERMANN ET AL.

Examiner

Nashaat T. Nashed, Ph. D.

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**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 05 August 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

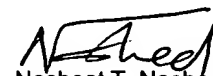
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1, 2 and 6-11.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

  
Nashaat T. Nashed, Ph. D.  
Primary Examiner  
Art Unit: 1656

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Claims 1, 2, and 6-11 are pending and under consideration.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, and 6-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility, see previous Office action mailed January 21, 2004, September 15, 2004, February 28, 2005, and May 5, 2005.

In response to the above rejection, applicants argue that: (a) the disclosure that the polypeptide of SEQ ID NO: 2 is a glycerol-3-phosphate acyltransferase enzyme, and that ATCR-1 molecules of the invention are capable of catalyzing the transfer of a fatty acyl CoA to the Sn-1 position of glycerol-3-phosphate; (b) the utility requirement is met with asserted utility which can include use as diagnostics and/or therapeutic for one or more disorder; and (c) reiterated their argument that the rejection is improper because the examiner did not follow the steps set forth in MPEP 2107 (II)(C).

Applicants' arguments filed August 5, 2005 have been fully considered, but they are found unpersuasive. In chemistry, the phrase "acyl" refers to any acyl radical of any organic acid including fatty acids. Thus, the phrase glycerol-3-phosphate acyl-transferase is interpreted as an enzymatic activity capable of transferring any acyl group which may include cholic acid, any fatty acid, having any carbon chain length or amino acid to either hydroxyl group of glycerol-3-phosphate. Enzymes are biocatalyst, which are characterized by substrate specificity and reaction stereo- and regioselectivity. Thus, said glycerol-3-phosphate acyltransferase is not a specific utility. Contrary to the applicant assertion, the utility requirement, is not satisfied by listing all the possible known uses of an acyl transferase, which include use as diagnostics and/or therapeutic for one or more unspecified disorder is not sufficient to meet the utility requirement. At page 9, lines 33-38, the specification refers to a substrate to be determined *in vivo* or *in vitro*. At page 10, lines 9-21, the specification gives the option to one of ordinary skill in the art the choice of eight unrelated utilities for the polypeptide. The utility requirement in a US application is not very high and does not require the full characterization of enzymatic or biological activity. Only a single credible specific or substantial utility is sufficient to overcome a utility rejection. Searching for a substrate, disease to be diagnosed or treated by the nucleic acid or the polypeptide would require further research. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Finally, applicants allege that the utility rejection is improper because the examiner allegedly did not follow the steps in MPEP 2107 (II)(C). Indeed, the examiner has followed the teaching of MPEP (see the restated rejection above). The examiner has

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accepted the asserted utility of an acyltransferase as required because he had no evidence to doubt such an assertion. The specification, however, does not teach a single use or function for the asserted utility. Applicants assert that one of ordinary skill in the art would know what to do with it because there are many known acyltransferases and the use of the polypeptide of SEQ ID NO: 2 should have the same uses. The examiner disagrees for reasons of record, and refers the applicant to the prior Office actions and the restated rejection above. It is true there are many known well-characterized acyltransferases and each of which has a specific chemical utility and biological function that is different from the others. Thus, the claims remain rejected.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

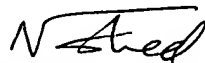
Claims 1, 2, and 6-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, see previous Office action mailed January 21, 2004, September 15, 2004, and February 28, 2005.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen M. Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Nashaat T. Nashed, Ph. D.  
Primary Examiner